

K063829

6 510(k) Summary or 510(k) Statement

510(k) SUMMARY FOR ALSIUS CORPORATION'S THERMOGARD AND CATHETER THERMAL REGULATION SYSTEM

Submitter's Name, Address, Telephone Number, and Contact Person

ALSIUS CORPORATION
15770 Laguna Canyon Road, Suite 150
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JAN 22 2007

Name of Device

The THERMOGARD and Catheter Thermal Regulation System.

Common or Usual Name

Central Venous Catheter (short term) and Thermal Regulating System.

Classification Name

FDA has classified the Alsius THERMOGARD/Alsius heat exchange catheters as Class II devices under 21 C.F.R. §§ 870.5900 - System, Hypothermia, Intravenous, Cooling. Classification Product Code: NCX.

Predicate Devices

The Alsius CoolGard 3000™ thermal regulating system.

Indications for Use

The THERMOGARD can be used with any of the Alsius Catheters. The indications for use are specific to the catheter. Please refer to the Indications for Use statement in the catheter specific Instructions for Use.

Indications for Use (K030421, K051912, K052443)

The THERMOGARD/Alsius Catheter Thermal Regulation System, using either the Icy™ or Fortius™ model catheter, is indicated for use:

- In cardiac surgery patients to achieve and or maintain normothermia during surgery and recovery/intensive care, and

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- To induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

Indications for Use (K014241, K051912)

The Alsius THERMOGARD™ and Cool Line™ Catheter Thermal Regulation System is indicated for use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

Table 1-1. Mortality by Diagnosis (ITT)

| | Cool Line | | | Control | | | p-value* |
|------|-----------|----|------|---------|----|------|----------|
| | n | N | % | n | N | % | |
| CI | 3 | 16 | 18.8 | 3 | 14 | 21.4 | 0.74 |
| ICH | 8 | 33 | 24.2 | 7 | 27 | 25.9 | 1.00 |
| PTBI | 10 | 44 | 22.7 | 4 | 38 | 10.5 | 0.24 |
| SAH | 13 | 61 | 21.3 | 7 | 63 | 11.1 | 0.15 |

*Fischer's exact test

For more details on the results of this study please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill Stroke Patient" #101416-001.

Technical Characteristics

The THERMOGARD and Catheter Thermal Regulation System consists of the THERMOGARD, a disposable Start Up Kit used to interface between the cooling bath of the THERMOGARD and the intravascular Catheter. The THERMOGARD is an integrated electro-mechanical heater/cooler that consists of a temperature monitor, a temperature controller unit, a heat exchanger unit, and roller pump. It supplies temperature controlled sterile saline to the indwelling Catheter that is placed percutaneously in the patient.

The technical characteristics of the Catheter are identical to the predicate device with the exception of revisions to the software that controls the device.

All models of Alsius Intravascular catheters are available for use with the THERMOGARD.

Principles of Operation

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The THERMOGARD system automatically adjusts the temperature of the heater/chiller saline bath to achieve the patient target temperature that has previously been set by the attending physician. This is done via data from a temperature probe in the patient that interfaces with the temperature controller. This principle of operation is identical to the predicate device.

Summary of the Basis for Finding of Substantial Equivalence

The THERMOGARD System is substantially equivalent to the Alsius CoolGard 3000™ heat exchange system in all its specifications.

Conclusion

In summary, descriptive information and performance data demonstrate that the Alsius THERMOGARD and Catheter Thermal Regulation System characteristics do not raise new questions of safety and effectiveness. Where appropriate, performance data demonstrate equivalence. The system in this revision acts as its own predicate device. The THERMOGARD and Catheter Thermal Regulation System is safe and effective when used in accordance with the Directions For Use and substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alsius Corporation
% Kenneth A. Collins, M.D.
Executive Vice President
15770 Laguna Canyon Road
Suite 150
Irvine, California 92618

JAN 22 2007

Re: K063829

Trade/Device Name: Alsius Thermogard and Catheter Thermal Regulation System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: II
Product Code: NCX
Dated: December 22, 2006
Received: December 26, 2006

Dear Dr. Collins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling as a box warning immediately following the indications for use statement:

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

Mortality by Diagnosis (ITT)

| | Cool Line | | | Control | | | p-value* |
|------|-----------|----|------|---------|----|------|----------|
| | n | N | % | n | N | % | |
| CI | 3 | 16 | 18.8 | 3 | 14 | 21.4 | 0.74 |
| ICH | 8 | 33 | 24.2 | 7 | 27 | 25.9 | 1.00 |
| PTBI | 10 | 44 | 22.7 | 4 | 38 | 10.5 | 0.24 |
| SAH | 13 | 61 | 21.3 | 7 | 63 | 11.1 | 0.15 |

*Fischer's exact test

For more details on the results of this study please refer to "Physician's Manual – Fever Reduction for Patients with Cerebral Infarction and Intracerebral Hemorrhage" #101416-001.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

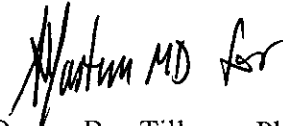
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its

Page 3 – Kenneth A. Collins, M.D.

toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
<http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Donna-Bea Tillman MD for". The signature is written in a cursive, flowing style.

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 063829

Device Name: Alsius Thermogard and Catheter Thermal Regulation System

Indications For Use:

Indications For Use:

Alsius Thermogard - Indications for Use:

The Alsius Thermogard and Cool Line™ Catheter Thermal Regulation System is indicated for use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

Mortality by Diagnosis (ITT analysis)

| | Cool Line | | | Control | | | |
|------|-----------|----|------|---------|----|------|------|
| | n | N | % | n | N | % | p* |
| CI | 3 | 16 | 18.8 | 3 | 14 | 21.4 | 0.74 |
| ICH | 8 | 33 | 24.2 | 7 | 27 | 25.9 | 1.00 |
| PTBI | 10 | 44 | 22.7 | 4 | 38 | 10.5 | 0.24 |
| SAH | 13 | 61 | 21.3 | 7 | 63 | 11.1 | 0.15 |

*Fischer's exact test

For more details on the clinical trial results please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill stroke patient" #101416-001.

Prescription Use X

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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Indications for Use

510(k) Number (if known):

Device Name: Alsius Thermogard and Catheter Thermal Regulation System

Indications For Use:

Fortius and Icy Catheters - Indications for Use:

The Alsius Thermogard/Alsius Catheter Thermal Regulation System, using either the Icy™ or Fortius™ model catheter, is indicated for use:

- in cardiac surgery patients to achieve and or maintain normothermia during surgery and recovery/intensive care, and
- to induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)